IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION	MDL No. 2775 Master Docket No. 1:17-2775 JUDGE CATHERINE C. BLAKE This Document Relates to: **All BHR-track cases**

MEMORANDUM

Among the plaintiffs in the Birmingham Hip Resurfacing (BHR) track of this hip implants product liability MDL are approximately 175 male patients who received BHR implants where the femoral head size was 50 mm or larger. Smith & Nephew now seeks summary judgment in all those cases on the basis that the plaintiffs have no expert testimony to support their remaining claims. For the reasons explained below, the court will grant the motion as to claims based on failure to warn the FDA; negligence and negligence per se claims based on failure to report, failure to train surgeons, and false advertising; and claims for punitive damages. The motion will be denied as to claims based on misrepresentations or breach of express warranty, because a fact-specific analysis of each case would be required.

BACKGROUND

Familiarity with prior rulings in this case, including the court's analysis of the preemption protection provided to Class III medical devices which have received PMA approval from the FDA, is assumed.[1] In 2006, the FDA granted pre-market approval to Smith & Nephew for the

[1] *See, e.g.*, *In re: Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation*, 300 F. Supp. 3d 732, 740 (D. Md. 2018) (granting in part and denying in part Smith & Nephew's motion to dismiss, finding the plaintiffs' strict liability claims preempted but allowing traditional state law claims to proceed); *In re: Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation*,

BHR, including femoral head sizes with diameters ranging from 38 mm to 58 mm, for use in both men and women. In 2010, a label change warned of risks for use of the BHR in female patients (generally) and for head sizes 44 mm and smaller in male patients. In 2015, Smith & Nephew voluntarily withdrew 46mm and smaller head sizes from the market and contraindicated the device for female patients generally. BHRs with larger head sizes (48 mm and above) remain on the market, with FDA approval, for implantation in men.[2]

ANALYSIS

I. Misrepresentation-based liability

In prior rulings, the court has found that only certain categories of claims can, at least facially, escape preemption. Among those categories, only negligent misrepresentation (or negligence based on misrepresentations) and breach of express warranty have survived for trial. *In re: Smith & Nephew BHR*, 300 F. Supp. 3d at 745; *Redick v. Smith & Nephew, Inc.*, No. 1:17-cv-00944, ECF 604 at 12, 19–27, 31–34 (D. Md. May 17, 2021); *Mosca v. Smith & Nephew*, No. 1:18-cv-03520, ECF 425 at 16–22, 25–26 (D. Md. July 19, 2021). In those cases, the plaintiffs' theory centered on Smith & Nephew's alleged misleading omission, in voluntary communications, of the higher risk of revision applicable to female patients and patients with small femoral head sizes. In the current motion, focusing first on the misrepresentation and breach of warranty claims, Smith & Nephew points to various statements by the plaintiffs' experts that do not criticize the use of larger femoral head sizes in male patients and do not identify any misrepresentation about the risk of revision in that population generally. *See, e.g.*,

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2021 WL 3617419, No. 1:17-cv-03677 (D. Md. Aug. 13, 2021) (granting Smith & Nephew's motion for summary judgment against plaintiff William Albritton); *In re: Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation*, No. 1:17-cv-1344 at ECF 570 (D. Md. Aug. 19, 2021) (granting Smith & Nephew's motion for summary judgment against plaintiff Aubrey Sedgwick).

[2] Smith & Nephew limits its motion to head sizes 50 mm or larger.

ECF 2762-4, Ex. B, Dr. Jeffrey Shapiro MDL Dep. of Sep. 11, 2020 at 208–11 (Plaintiffs' general causation expert testifying that BHR implants in men with large femoral head sizes are "doing well, if not better than the traditional metal on poly" hip implant); ECF 2762-6, Ex. D, Shapiro Albritton Dep. of Mar. 23, 2021 at 211–12 (testifying that he did not believe Smith & Nephew had made misrepresentations to surgeons with respect to large femoral head size BHR implants); ECF 2762-12, Ex. J, Dr. Yadin B. David Expert Report at 23, 35 (Plaintiffs' design expert concluding that a "reasonably prudent medical device manufacturer in Smith & Nephew's position would not have continued to promote the BHR for women and patients with 46 mm head size and below"); ECF 2762-13, Ex. K, Larry Spears Expert Report at 11–12, 19, 23 (Plaintiffs' regulatory expert speaking only of implants in women and patients with femoral head sizes 46 mm and below).

The plaintiffs have responded, however, by pointing to expert opinions identifying subgroups of the male large femoral head size population for whom there is an increased risk of revision. Those include patients with avascular necrosis ("AVN"), high BMI (obesity), a high abduction angle, and patients above 65 years old. *See, e.g.*, ECF 3175-1, Shapiro report at 16, 26, 27, 33; ECF 3175-3, Mari Truman's Engineer's report at 46 (ECF page numbering 47 of 273), 50, 54.[3] The plaintiffs argue that Smith & Nephew, in its voluntary communications, misled patients and/or their doctors about these increased risks. Indeed, the court relied on the presence of AVN as a risk factor for plaintiff William Albritton in ruling that he may have proffered an actionable misrepresentation, although summary judgment nonetheless was granted because his surgeon had not relied on any marketing statements by Smith & Nephew. *Albritton*, No. 1:17-

[3] Truman cites to Smith & Nephew documents in her report.

md-2775, ECF 2962 at 10-11.[4] The plaintiffs also have identified, as potentially actionable misrepresentations that would be applicable to all patients generally, the supposed greater ease of revision surgery after a BHR than after a THA[5] and the superiority of the "as-cast" metallurgy process.[6]

The court agrees with Smith & Nephew that summary judgment may be appropriate across all cases (or a category of cases) in an MDL, but only where a finding can be made as a matter of law applying to all cases in the MDL, such as a failure to prove general causation. *In re: Lipitor (Atorvastatin Calcium) Marketing, Sales Practice, and Products Liability Litigation (No. II) MDL 2502*, 892 F.3d 624, 648 (4th Cir. 2018); *In re: Mirena IUS Levonorgestrel-Related Products Liability Litigation (No. II)*, 387 F. Supp. 3d 323, 358 (S.D.N.Y. 2019) *aff'd* 982 F.3d 113 (2d Cir. 2020). While it is clear that the greater weight of the plaintiffs' experts' opinions is directed at the increased risk of revision for female patients and those receiving

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[4] "The court does not believe [plaintiff William Albritton's expert's concessions that Smith & Nephew had not made any misrepresentations regarding the risk of revision for larger head sizes] are dispositive, as Mr. Albritton's claims are premised on alleged misrepresentations as to the risk of revision to him as a patient with AVN." *Albritton v. Smith & Nephew, Inc.*, No. 1:17-cv-3677, ECF 500 at 10 or No. 1:17-md-2775, ECF 2962 at 10 (D. Md. Aug. 13, 2021).

[5] *See, e.g.*, *Sedgwick*, No. 1:17-md-1775 ECF 2757-4, Patient's Guide at 14 ("[I]f your surgeon should determine you need to have your Birmingham Hip implant replaced at some point in the future, you may undergo a regular total hip replacement surgery. If you had originally undergone total hip replacement instead of hip resurfacing, you would be dealing with a more traumatic and complex procedure and you would be receiving a more invasive implant."; cited in *Sedgwick* Mot. Summ. J. ECF 2757-1 at 5 and Reply ECF 2842 at 5). *Cf.* ECF 3323-11, Ex. J, Expert Report of Dr. Michael A. Mont at 16 ("[T]he patient who is revised from a resurfacing device to a THA device for the femoral part of the case is in the same position that they would have been had they elected a THA surgery to begin with.").

[6] *See, e.g.*, ECF 2386-3, Ex. A, Expert Report of Dr. Jeffrey Shapiro at 31 (observing that Smith & Nephew focused on material and metallurgy to claim that the BHR was superior to other metal-on-metal designs and had the best wear characteristics); ECF 2387-3, Ex. A, Scott Marshall Materials Engineering Report at 11 ¶¶ 10–12 (as-cast cobalt chromium alloy deteriorates and has not proven superior to heat-treated cobalt chromium alloy for the subject application); *Sedgwick*, No. 1:17-md-2775 ECF 2757-5, Dep. Dr. Boucher at 154–56 (Feb. 7, 2020) (surgeon recounting Smith & Nephew training programs extolling the metallurgic advantages of as-cast vs. heat-treated manufacturing); ECF 3294-3, Exhibit B, Patient's Guide at 32-33 (describing reduced joint wear for the BHR's ball and socket compared to traditional hip implant materials); ECF 3175 at 8 (citing physician deposition testimony in *Habegger v. Smith & Nephew, Inc.*, No. 1:18-cv-3394, Dep. Dr. Graybill at 30–32 (Aug. 3, 2020) (testifying that Smith & Nephew's data suggested, and doctors were told, that the as-cast rather than heat-treated product was superior) and *Steyer v. Smith & Nephew, Inc.*, 1:18-cv-2411, Dep. Dr. Dungy at 37 (March 4, 2020) (Smith & Nephew had "figured out a way to machine it better so it wouldn't fall apart")).

smaller femoral head sizes, it is not clear that none of the 175 plaintiffs at issue would be able to advance a potentially actionable misrepresentation sufficient to survive summary judgment.

In challenging the sufficiency of plaintiffs' counsel's Rule 56(d) affidavit in its reply memorandum and at oral argument, Smith & Nephew argued that counsel should be able to proffer a specific misrepresentation as to each individual plaintiff without additional discovery, based on their access to their own clients. (ECF 3323, Def.'s Reply Mem. Supp. Mot. Summ. J. at 4-5; ECF 3479, Tr. Oral Arg. Mot. Summ. J. at 23–25). That may be true, but it illustrates that the court is in essence being asked to rule on 175 individual summary judgment motions. Indeed, if the plaintiffs came forward with such alleged misrepresentations based simply on their own clients' recollections, there is no doubt Smith & Nephew would challenge their adequacy.

II. Other theories of liability

As to other theories of liability, however, including failure to warn the FDA, and negligence and negligence per se claims based on failure to report adverse events, failure to train surgeons, and "misbranding" predicated on any statement in the FDA-approved label, claims as to which summary judgment was granted in *Redick* and *Mosca*, the court agrees that the plaintiffs failed to offer any argument in their responses (ECF 3175, Pls.' Position Statement; ECF 3294, Pls.' Mem. Response) that would support allowing such claims to proceed as to males implanted with large femoral head sizes, nor did they do so when given the opportunity at oral argument. (ECF 3479 at 11:16–25, 27:24–45:14). Similarly, they offered no support for the award of punitive damages in such cases, particularly considering that the BHR devices with large femoral head sizes remain on the market as FDA approved devices. Summary judgment is appropriate for those claims. *See Mentch v. E. Sav. Bank, FSB*, 949 F. Supp. 1236, 1247 (D. Md. 1997) (where the plaintiff abandoned a claim by failing to address that claim in her opposition to

the defendant's motion for summary judgment or to clarify in response to the defendant's reply brief); *Young v. Swiney*, 23 F. Supp. 3d 596, 601 (D. Md. 2014).

CONCLUSION

For the foregoing reasons, the court will grant the motion as to claims based on failure to warn the FDA; negligence and negligence per se claims based on failure to report, failure to train surgeons, and false advertising; and claims for punitive damages. The motion will be denied as to claims based on misrepresentations or breach of express warranty. A separate Order follows.

2/28/22
Date

CCB
Catherine C. Blake
United States District Judge